

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q94782

Miki KOBAYASHI, et al.

Appln. No.: Based on PCT/JP04/017521

Confirmation No.: Unknown

Group Art Unit: Unknown

Filed: May 22, 2006

Examiner: Unknown

For: AGENT FOR TREATING CHRONIC PELVIC PAIN SYNDROME

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.97 and 1.98

MAIL STOP AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith, except for the following: U.S. patents and/or U.S. patent publications; and co-pending non-provisional U.S. applications filed after June 30, 2003.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

10/580417
IAP9 Rec'd PCT/PTO 22 MAY 2006

INFORMATION DISCLOSURE STATEMENT
U.S. Appln. No.: Based on PCT/JP04/017521
Attorney Docket No.: Q94782

In compliance with the concise explanation requirement under 37 C.F.R. § 1.98(a)(3) for foreign language documents, Applicant encloses herewith a copy of a Communication from a foreign patent office in a counterpart application citing such documents (International Search Report for PCT/JP04/017521 dated December 28, 2004), together with an English-language version (if not already included) of at least that portion of the Communication indicating the degree of relevance found by the foreign patent office. English language abstracts, submitted herewith, constitute concise statements of relevance for Japanese Patent Application Publication Numbers 11-292878 and 11-292877.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

Mark Boland / Bruce Kram
Mark Boland / Reg. No. 33,725
Mark Boland
Registration No. 32,197

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Date: May 22, 2006

Substitute for Form 1449 A & B/PTO				Information Disclosure Statement by Applicant (use as many sheets as necessary)																																																			
				Information Disclosure Statement by Applicant (use as many sheets as necessary)																																																			
Sheet 1 of 2				Attorney Docket Number Q94782																																																			
<table border="1"> <tr> <td colspan="6">U.S. PATENT DOCUMENTS</td> </tr> <tr> <th rowspan="2">Examiner Initials*</th> <th rowspan="2">Cite No.¹</th> <th colspan="2">Document Number</th> <th rowspan="2">Publication Date MM-DD-YYYY</th> <th rowspan="2">Name of Patentee or Applicant of Cited Document</th> </tr> <tr> <th>Number</th> <th>Kind Code² (if known)</th> </tr> <tr> <td></td> <td></td> <td>US 5,712,298</td> <td>A</td> <td>01-27-1998</td> <td>Hermann Amschler</td> </tr> <tr> <td></td> <td></td> <td>US 6,740,662</td> <td>B1</td> <td>05-25-2004</td> <td>Masahiro Iwata, et al.</td> </tr> <tr> <td></td> <td></td> <td>US 2004/0192701</td> <td>A1</td> <td>09-30-2004</td> <td>Masahiro Iwata, et al.</td> </tr> <tr> <td></td> <td></td> <td>US 5,817,670</td> <td>A</td> <td>10-06-1998</td> <td>Kazuhisa Takayama, et al.</td> </tr> <tr> <td></td> <td></td> <td>US 6,136,810</td> <td>A</td> <td>10-24-2000</td> <td>Kazuhisa Takayama, et al.</td> </tr> <tr> <td></td> <td></td> <td>US 6,544,983</td> <td>B2</td> <td>04-08-2003</td> <td>Annette Doherty</td> </tr> </table>						U.S. PATENT DOCUMENTS						Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Number	Kind Code ² (if known)			US 5,712,298	A	01-27-1998	Hermann Amschler			US 6,740,662	B1	05-25-2004	Masahiro Iwata, et al.			US 2004/0192701	A1	09-30-2004	Masahiro Iwata, et al.			US 5,817,670	A	10-06-1998	Kazuhisa Takayama, et al.			US 6,136,810	A	10-24-2000	Kazuhisa Takayama, et al.			US 6,544,983	B2	04-08-2003	Annette Doherty
U.S. PATENT DOCUMENTS																																																							
Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document																																																		
		Number	Kind Code ² (if known)																																																				
		US 5,712,298	A	01-27-1998	Hermann Amschler																																																		
		US 6,740,662	B1	05-25-2004	Masahiro Iwata, et al.																																																		
		US 2004/0192701	A1	09-30-2004	Masahiro Iwata, et al.																																																		
		US 5,817,670	A	10-06-1998	Kazuhisa Takayama, et al.																																																		
		US 6,136,810	A	10-24-2000	Kazuhisa Takayama, et al.																																																		
		US 6,544,983	B2	04-08-2003	Annette Doherty																																																		

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code ² (if known)		
		US 5,712,298	A	01-27-1998	Hermann Amschler
		US 6,740,662	B1	05-25-2004	Masahiro Iwata, et al.
		US 2004/0192701	A1	09-30-2004	Masahiro Iwata, et al.
		US 5,817,670	A	10-06-1998	Kazuhisa Takayama, et al.
		US 6,136,810	A	10-24-2000	Kazuhisa Takayama, et al.
		US 6,544,983	B2	04-08-2003	Annette Doherty

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation ⁶
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)			
		WO	99/57303	A1	11-11-1999	UNIVERSITY OF MARYLAND-BALTIMORE	
		WO	95/24381	A1	09-14-1995	SMITHKLINE BEECHAM CORPORATION	
		WO	01/87281	A2	11-22-2001	SMITHKLINE BEECHAM P.L.C.	
		JP	11-292878	A	10-26-1999	Yamanouchi Pharm. Co. Ltd.	Abstract
		JP	11-292877	A	10-26-1999	Yamanouchi Pharm. Co. Ltd.	Abstract

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation ⁶
		ARMIN HATZELMANN, et al., "Anti-Inflammatory and immunomodulatory Potential of the Novel PDE4 Inhibitor Roflumilast in Vitro", The Journal of Pharmacology and Experimental Therapeutics, 2001, pp. 267-279, Vol. 297, No. 1	
		"Summary of the National Institute of Arthritis, Diabetes, Digestive and Kidney Diseases Workshop on Interstitial Cystitis, National Institutes of Health, Bethesda Maryland", The Journal of Urology, August 28-29, 1987, pp. 203-206, Vol. 140	
		S. LARSEN, et al., "Mast Cells in Interstitial Cystitis", British Journal of Urology, 1982, pp. 283-286, Vol. 54	
		J. KASTRUP, et al., "Histamine Content and Mast Cell Count of Detrusor Muscle in Patients with Interstitial Cystitis and Other Types of Chronic Cystitis", British Journal of Urology, 1983, pp. 495-500, Vol. 55	
		TETSUO YAMADA, et al., "Alternate occurrence of Allergic Disease and an Unusual Form of Interstitial Cystitis", Int. J. Urol. 1998, pp. 329-336, Vol. 5	
		DEBORAH R. ERICKSON, et al., "Inflammatory Cell types and Clinical Features of Interstitial Cystitis", The Journal of Urology, 1997, pp. 790-793, Vol. 158	
		DEBORAH R. ERICKSON, "Urine Markers of Interstitial Cystitis", Urology, 2001, pp. 15-21, Vol. 57	
		H. RICHARD HELLSTROM, et al., "Eosinophilic Cystitis", A.J.C.P., November 1979, pp. 777-784, Vol. 72, No. 5	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or follow the hyperlink from the title of the document to the internet. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to indicate here if English language Translation is attached.

IAP9 Rec'd PCT/PTO 22 MAY 2006

Substitute for Form 1449 A & B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Application Number	Based on PCT/JP04/017521
				Confirmation Number	Unknown
				Filing Date	May 22, 2006
				First Named Inventor	Miki KOBAYASHI
				Art Unit	Unknown
				Examiner Name	Unknown
Sheet	2	of	2	Attorney Docket Number	Q94782

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code ² (if known)		
	US				

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Country Code ³	Number ⁴		

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.				Translation ⁶
		JAMES A. KOZIOL, et al., "The Natural History of Interstitial Cystitis; A Survey of 374 Patients", The Journal of Urology, March 1993, pp. 465-469, Vol. 149				
		MADHU ALAGIRI, et al., "Interstitial Cystitis: Unexplained Associations with Other Chronic Disease and Pain Syndromes", 1997, pp. 52-57, Vol. 49				
		ERIC ROVNER, et al., "Treatments used in Women with Interstitial Cystitis: The Interstitial Cystitis Data Base (ICDB) Study Experience", Adult Urology, 2000, pp. 940-945, Vol. 56, No. 6				
		THEOHARIS C. THEOHARIDES, et al., "New agents for the medical treatment of interstitial cystitis", Exp. Opin. Invest. Drugs, 2001, pp. 521-546				
		"NIH Consensus Definition and Classification of Prostatitis", JAMA, July 21, 1999, pp. 236-237, Vol. 281, No. 3				
		IRFAN ORHAN, et al., "Seminal plasma cytokine levels in the diagnosis of chronic pelvic pain syndrome", International Journal of Urology, 2001, Vol. 8, pp. 495-499				
		RICHARD B. ALEXANDER, et al., "Autoimmune Prostatitis: Evidence of T Cell Reactivity with Normal Prostatic Proteins", Adult Urology, 1997, pp. 893-899, Vol. 50, No. 6				
		JANE L. MILLER, et al., "Prostatodynia and Interstitial Cystitis: one and the same?", Adult Urology, April 1995, pp. 587-590, Vol. 45, No. 4				
		THEODORE J. TORPHY, "Phosphodiesterase Isozymes", Am. J. Respir. Crit. Care Med., 1998, pp. 351-370, Vol. 157				
		SCOTT H. SODERLING, et al., "Regulation of cAMP and cGMP signaling: new phosphodiesterases and new functions", Curr. Opin. Cell Biol., 2000, pp. 174-179				
		DAVID M. ESSAYAN, "Molecular mechanisms in allergy and clinical immunology", J. Allergy Clin. Immunol., November 2001, pp. 671-680				
		MAURO M. TEIXEIRA, et al., "Phosphodiesterase (PDE)4 inhibitors: anti-inflammatory drugs of the future?", TiPS, May 1997, pp. 164-170, Vol. 18				
		JOHN E. SOUNESS, et al., "Immunosuppressive and anti-inflammatory effects of cyclic AMP phosphodiesterase (PDE) type 4 inhibitors", Immunopharmacology, 2000, pp. 127-162, Vol. 47				
		DAVID C. UNDERWOOD, et al., "Antiasthmatic Activity of the Second-Generation Phosphodiesterase 4 (PDE4) Inhibitor SB 207499 (Ariflo) in the Guinea Pig", The Journal of Pharmacology and Experimental Therapeutics, 1998, pp. 968-995, Vol. 287, No. 3				
		International Search Report for PCT/JP04/017521 dated December 28, 2004				

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or follow the hyperlink from the title of the document to the internet. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to indicate here if English language Translation is attached.